IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

AFFYMETRIX, INC., a Delaware corporation,

Plaintiff and Counterdefendant,

v.

MULTILYTE LTD., a British corporation,

Defendant and Counterclaimant.
/

No. C 03-03779 WHA

ORDER GRANTING SUMMARY JUDGMENT OF NON-INFRINGEMENT UNDER DOCTRINE OF EQUIVALENTS

INTRODUCTION

Pursuant to the order of May 17, 2005, plaintiff Affymetrix, Inc. now moves for summary judgment of non-infringement under the doctrine of equivalents based on the claim terms "binding agent" and "binding site." This motion is **GRANTED**.

STATEMENT

Defendant Multilyte Ltd. is the assignee of the three patents-in-suit: United States Patent Nos. 5,599,720 ("the '720 patent"), 5,432,099 ("the '099 patent") and 5,807,755, ("the '755 patent"). Affymetrix manufactures and sells DNA microarray systems which utilize oligonucleotide probes to detect the presence of complementary target strands via hybridization. There is no dispute that the accused products, whether used for RNA analysis or DNA analysis, only involve interactions between nucleic acids.

On February 22, 2005, the claim term "binding agent" was construed to mean "a molecule used in an immunoassay that is capable of binding to an analyte and has an affinity constant (measured at equilibrium) of 10^{13} liters/mole or less." Because there was insufficient

information in the record at that time, that order declined to rule whether nucleic acids and oligonucleotides were "binding agents."

At a status conference later held on March 3, 2005, however, Multilyte insisted that explicitly including (or excluding) oligonucleotides from the definition of binding agent would be "case dispositive." Mr. Lex Brainerd, speaking on behalf of Multilyte, persuaded the Court that a second round of claim construction would be worthwhile (March 3, 2005 Hearing Tr. at 3:13–23; 4:10–17; 7:14–18):

> As we set forth in our portion of the status conference statement, the whole issue of "binding agent" and its ultimate claim construction, which I know you have left open for the reasons stated in your order, is really the issue that is going to drive this case.
>
> "Binding agent" appears in every claim of all three patents. A resolution of the remaining claim construction issue, which you left open, which is whether or not "binding agent" would capture or include nucleic acids, in our opinion, it's a, for want of a better word, kind of a case-dispositive issue.
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> * * *
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> Very frankly, if we win, we are happy to go to trial November 7th. If we lose, then I think the most efficient thing is for us to find some way to enter into a stipulated judgment and take this matter to the Federal Circuit. Our goal here is to move forward as efficiently as possible. If we can take the matter to trial, fine, so be it. If we have to seek relief elsewhere, then we ought to know that as quickly as possible and we can efficiently go in that direction.
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> * * *
>
> The most efficient way to move is to do that [further claim construction on the term "binding agent"]. And then if we lose then, very frankly, then we would, as indicated in our response to your request, the status conference statement, we would probably find a way to enter some kind of a stipulated judgment or some kind of a judgment and move on.

Based thereon, Multilyte was granted leave to file a motion for further claim construction of "binding agent." Meanwhile, Affymetrix was granted leave to file two motions for summary judgment of non-infringement: (1) based on the phrases "determining the ambient concentrations" and "loading a plurality of different binding agents . . . onto a support means" and (2) based on the term "binding agent." These motions were briefed simultaneously.

Another hearing was held on all three motions, at which the parties focused primarily on the further claim construction of "binding agent." As previously noted in another order, the parties were expected to argue whether "binding agent," as already defined, would include or exclude oligonucleotides or other molecules comprised of nucleic acids. Instead, Multilyte took

advantage of the opportunity for further claim construction to move for *reconsideration*, arguing that the "immunoassay" limitation had improperly restricted the invention to the preferred embodiment, namely antibodies.*

On April 28, 2005, the Court re-construed the term "binding agent" to mean "a molecule conventionally having one or at most two binding sites and an affinity constant (measured at equilibrium) of 10^{13} liters/mole or less." That order also construed the term "binding site," as it would be understood by a person of ordinary skill in the relevant art, to mean a structurally and functionally distinct region of a *protein*. Contrary to Multilyte's contentions, a non-scientific definition of "binding site" — *i.e.*, any site where binding occurs, such as the region within a nucleic acid sequence recognized by a protein or protein complex — was explicitly rejected.

Thus, the term "binding agent" was expressly defined to include certain molecules, but exclude others:

> To avoid any possible confusion, this order clarifies that this definition of "binding agent" includes (but is not limited to) antibodies, binding proteins and receptor preparations. On the other hand, this definition does *not* encompass DNA, RNA, oligonucleotides or any other molecules comprised solely of nucleic acids.

(Order Granting Multilyte's Motion for Further Claim Construction and Re-Construing "Binding Agent," April 28, 2005, at 5:3–6). In a separate order, summary judgment of non-infringement was also granted based on the phrases (1) "binding agent" and (2) "loading a plurality of different binding agents . . . onto a support means," the latter of which was unopposed. Judgment was entered accordingly.

Contrary to its prior representation that a further round of claim construction would be "case dispositive," Multilyte then reversed field and sought yet more proceedings. Multilyte moved to alter or amend the judgment, on the basis that even if the accused products did not literally infringe, the Court "failed to consider" the question of infringement under the doctrine

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* The first claim-construction order had relied upon a representation by Multilyte's counsel at oral argument that the other types of binding agents referenced in the '720 patent (*i.e.*, binding proteins and receptor preparations) were also molecules used in immunoassays (Feb. 16, 2005 Hearing Tr. at 32:18–25). In the opening brief on Multilyte's motion for further claim construction, however, counsel confessed that this was scientifically inaccurate.

of equivalents. The doctrine of equivalents had never been raised by Multilyte in the summary-judgment briefs or at the hearing.

Nonetheless, Multilyte's motion was granted. In an order dated May 17, 2005, the Court expressly declined to engage in a third round of claim construction, but the case file was re-opened and the parties were given the opportunity to brief the issue of infringement under the doctrine of equivalents in light of the revised definition of "binding agent."

ANALYSIS

Because reexamination proceedings for all three patents are still ongoing, any finding of *infringement* would be premature because it is not yet known which claims, if any, will emerge from the reexamination process. Summary judgment of *non-infringement*, in contrast, would be appropriate if the Court finds that the accused products would not infringe no matter what claims are issued. Here, the parties agree that the term "binding agent" will appear in any claim that ultimately issues. As previously ruled, the accused products do not literally infringe the "binding agent" limitation of the asserted claims. The question now is whether Affymetrix is also entitled to a declaratory judgment that its products are non-infringing under the doctrine of equivalents. This order finds in the affirmative.

An accused product that does not literally infringe upon the express terms of a patent may nonetheless infringe under the doctrine of equivalents. *See generally Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). Regardless of whether the tripartite "function-way-result" test or an "insubstantial differences" approach is used, the central inquiry remains whether the accused product embodies each and every element of the claimed invention, either literally or by an equivalent. *Id.* at 39–40.

Yet, there are various legal limitations on the application of this doctrine. For example, "if prosecution history estoppel would apply or if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further *material* issue for the jury to resolve." *Id.* at 39 n.8 (emphasis in original). Likewise, "the concept of equivalency cannot embrace a structure that is specifically

excluded from the scope of the claims." *Dolly, Inc. v. Spaulding & Evenflo Cos., Inc.*, 16 F3d 394, 400 (Fed. Cir. 1994).

The specific exclusion principle applies regardless of whether the exclusion is express or implied. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345–47 (Fed. Cir. 2001)(discussing various decisions on this principle, and its corollary, the "all limitations" rule). A particular structure may be specifically excluded from the scope of the patented invention by the claims either as they are written or as they are construed by the Court.

The simplest application of the specific exclusion principle arises where the claim language itself excludes certain structures. *See, e.g.*, *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005)(holding that use of the term "mounted" in the claim language specifically excluded structures that were unmounted). Yet the Federal Circuit has also found that the doctrine of equivalents cannot be used to expand the scope of a claim where certain structures have been excluded during claim construction. *See, e.g.*, *Athletic Alternatives v. Prince Mfg., Inc.*, 73 F.3d 1573, 1582 (Fed. Cir. 1996)(construing "varies between" to require at least three different splay-creating offset distances and finding that a two-distance splayed string system was specifically excluded from the scope of the claims).

In one particularly instructive example, the district court judge granted summary judgment of non-infringement because allowing the patentee to assert that hydrosols which form in the stomachs of patients infringe under the doctrine of equivalents would "eviscerate a claim limitation." The term "hydrosol" had previously been construed (in relevant part) to mean "a synthetic pharmaceutical preparation, *i.e.*, it does not encompass a dispersion of solid particles of cyclosporin which only forms in the stomach of a patient." *Novartis Pharms. Corp. v. Eon Labs Mfg., Inc.*, 234 F.Supp.2d 464, 468–69 (D. Del. 2002), *affirmed*, 363 F.3d 1306, 1312 (Fed. Cir. 2004).

Affymetrix correctly argues that the specific exclusion principle would preclude a jury's finding of infringement under the doctrine of equivalents as a matter of law. Because the Court's definition of "binding agent" and "binding site" specifically excludes certain types of molecules containing *zero* binding sites, Multilyte may not assert that assays using these

molecules infringe under the doctrine of equivalents. Put simply, if a "binding agent" must be a protein or protein fragment, a non-protein molecule cannot be an equivalent without vitiating this claim element. *See SciMed,* 242 F.3d at 1347 ("[I]f a patent states that the claimed device must be 'non-metallic,' the patentee cannot assert the patent against a metallic device on the ground that a metallic device is equivalent to a non-metallic device.").

Multilyte contends that whether oligonucleotides perform substantially the same function, in substantially the same way, to achieve substantially the same result as proteins is a question of fact for the jury. Not so. Even if this case proceeded to trial on the present record, Multilyte would not be permitted to invoke the doctrine of equivalents to encompass the accused oligonucleotide assays because of the specific exclusion principle. Regardless of any jury verdict rendered, Affymetrix would be entitled to judgment as a matter of law on the issue of infringement. *Compare Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1337–39 (Fed. Cir. 2004)(reversing claim construction, but affirming the district court's application of the specific exclusion principle to grant judgment as a matter of law after the jury found infringement).

It is true, as Multilyte argues, that "[l]iteral failure to meet a claim limitation does not necessarily amount to 'specific exclusion.'" *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 149 F.3d 1309, 1317 (Fed. Cir. 1998). Of course, the question of infringement under the doctrine of equivalents always focuses on subject matter that does not literally fall within the scope of the asserted claim. But even *Ethicon* recognizes that such subject matter would not be covered under the doctrine of equivalents if, as here, "its inclusion is somehow inconsistent with the language of the claim." *Ibid.*

Moreover, its reliance on *Aclara* is unconvincing. There, Judge Charles Breyer reasoned that summary judgment was inappropriate because a jury could find a covered structure equivalent even where the term "trench" had been construed to mean "an uncovered structure such as a ditch." In reaching his decision, he noted that it was "extraordinarily difficult to resolve this dispute" and that "Federal Circuit cases do not provide much guidance." *Aclara Biosciences, Inc. v. Caliper Techs. Corp.*, 2000 WL 1639507, at *9–14 (N.D. Cal.

2000). Since Judge Breyer wrote *Aclara*, however, the Federal Circuit has revisited this issue, such that the undersigned now has the benefit of the more recent decisions cited above.

This order must note that after the first round of claim construction, it was *Multilyte* that pressed the Court to engage in further claim construction and provide a definition that categorically included or excluded oligonucleotides (see March 3, 2005 Hearing Tr. at 3:19–23). Yet, now that "binding agent" has been construed to exclude oligonucleotides, it attempts to argue that the "specific-exclusion" principle does not apply; in short, it characterizes these clarifications as "findings of no literal infringement, not further claim construction" (Opp. 5). Ironically, although Multilyte itself proffered numerous items of extrinsic evidence to demonstrate what "binding agent" and "binding site" meant to a person of ordinary skill in the relevant art, it now asserts that any reference to such materials would be improper (*id.* at 5–6).

Multilyte is being too nimble. It cannot change its mind simply because the process of further claim construction it requested did not produce a result in its favor. Indeed, had "binding agent" been re-construed to categorically include oligonucleotides or all biological molecules, Multilyte itself would have characterized this as further claim construction, rather than infringement analysis. In response to the Court's concern that Multilyte was seeking a definition that would necessarily compel a finding of infringement, counsel admitted that infringement would still need to be proven, even "with 'binding agent' *construed*, for the purposes of this discussion, in our favor" (March 3, 2005 Hearing Tr. at 6:16–18)(emphasis added).

In summary, the order re-construing "binding agent" could not have been more clear that the explicit exclusion of DNA, RNA, oligonucleotides or any other molecules comprised solely of nucleic acids was part of the definition. In fact, the finding of no literal infringement was reached in a completely separate order.

As described above, the Court has already engaged in two rounds of claim construction. At this point, any argument that "binding agent," "binding site" or other claim terms were improperly construed should be presented to the Federal Circuit, as claim construction is reviewed *de novo* upon appeal.

CONCLUSION

For the foregoing reasons, plaintiff's motion for summary judgment of non-infringement under the doctrine of equivalents is **GRANTED**. As counsel raised no objections during the hearing, the claims of patent invalidity and unenforceability are hereby **DISMISSED**, without prejudice to Affymetrix re-asserting them in the event of a remand. At this time, final judgment will be entered, so this action may proceed to the Federal Circuit for appellate review.

IT IS SO ORDERED.

Dated: June 23, 2005

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE